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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,062	10/19/2001	David Rizzieri	20605/1203866-US1	5735

7590 12/01/2006  
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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/008,062	<b>Applicant(s)</b> RIZZIERI ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,12-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,12-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/12/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Application/Control Number: 10/008,062	Page 2
Art Unit: 1642	

## DETAILED ACTION

### *Response to Arguments and Amendments*

1. Remarks were submitted September 11, 2006. The claim status section of the Remarks was not correct. Claim 21 was cancelled, as well as claim 11. Reflection of the current status of the claims is cited below.

2. Claims 1-6, 8-10, 12-20 and 22-25 are pending.

Claims 1, 12, 22 and 23 have been amended.

Claim 25 has been added.

Claims 11 and 21 have been cancelled.

Claims 1-6, 8-10, 12-20 and 22-25 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Maintained Rejections*

#### *Claim Rejections - 35 USC § 112*

4. The rejection of claims 4, 12-22, 24 and newly added claim 25 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or

Application/Control Number: 10/008,062	Page 3
Art Unit: 1642	

complete evidence of the deposit of the biological materials is maintained and newly made.

Applicants reassert, "the present invention is directed to the new use of a known compound.", see page 7, first full paragraph of Remarks submitted September 11, 2005. Applicants also aver the <sup>131</sup>I-labeled chimeric 81C6 monoclonal antibody was described in U.S. Patent No. 5,624,659 and the patent file reveals the antibody's sequence. Applicants conclude arguments noting they are willing to deposit the hybridoma that produces the 81C6 antibody in a recognized depository once the claims are deemed allowable. These points of view and arguments have been considered, but found unpersuasive.

Until the assurances under the Budapest Treaty and/or deposit are met in the instant application the instant rejection is made and maintained for the reasons of record.

### ***Claim Rejections - 35 USC § 103***

5. The rejection of claims 1-6, 8-24 and newly added claim 25 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,624,659 (April 29, 1997/ reference 1 from IDS submitted June 14, 2002), and in view of Rizzieri et al. (Blood 94(10), Part 2, Supplement 1: 4339, Abstract #4339 November 1999/ reference 3 from IDS submitted June 14, 2003) is maintained and newly made.

Applicants set forth the criteria needed to establish a *prima facie* case of obviousness, see page 8 of the Remarks. Applicants assert the currently amended

Art Unit: 1643

claims including the requirement that the lymphoma will be treated with an antibody to tenascin is administered intravenously or intra-arterially is not taught by the prior art references, see page 8, section A. This particular type of administration does not preclude one of ordinary skill in the art from implementing the teachings of both references. Applicants' arguments encompass information and observations regarding brain cancer treatment implementing the monoclonal antibody 81C6. These arguments are not commensurate in scope. All of Applicants' arguments and supporting documents read on gliomas and intracranial malignancies, see bridging paragraph of pages 10 and 11 of the Remarks. The instant claims read on treating lymphoma. Not only are the arguments not commensurate because they read on a patentably distinct tumor type and as noted in the Action mailed March 10, 2006, but also because the radiosensitivity displayed by a solid tumor opposed to a hematological cancer is dissimilar as noted in the bridging paragraph of pages 5 and 6. And while the cited references may have shown to be unsuccessful in treating brain tumors there not sufficient information teaching away from the combination of the prior art. Applicants continue to assert their claimed method demonstrated unexpected and unobvious results, see bridging paragraph of pages 13 and 14. These points of view are not persuasive for the reasons of record, see bridging paragraph of pages 5 and 6 of Action mailed March 10, 2006.

The combination of the prior art references' teachings would have lead one of ordinary skill in the art to arrive at the claim invention at the time with a reasonable expectation of success. Both references provide suggestion and motivation to establish

Art Unit: 1643

and arrive at the claimed invention, accordingly the rejection is maintained and made, see the Action mailed March 10, 2006.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

Art Unit: 1643

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
21 November 2006